human or non-human animal body for medical or related purposes and is **formed from a coral of the *species Acropora grandis***."

In support of the rejection of this claim, the Examiner states that: "White *et al.* disclose a coralline hydroxyapatite material used as a bone substitute material in oral, periodontal and craniofacial surgery, and orthopaedic applications. The coralline material can be obtained from coral such as *Acropora*."

The Examiner's statement is incorrect because White does not disclose a shaped product formed from coral as claimed by applicant. White discloses a synthetic phosphate material, which can be prepared from a porous calcium carbonate material such as coral. However, as described at column 4, lines 9-12 of White, the calcium carbonate material is not used to produce the bone substitute material. Instead, the bone substitute material "is converted into whitlockite and hydroxyapatite by hydrothermal chemical exchange with a phosphate donor." In addition, the synthetic phosphate material is "infiltrated" by a monomer or prepolymer which is then thermally polymerized to strengthen the material (see column 2 line 60 to column 3 line 25). Thus, White does not disclose a product shaped from the coral itself, rather White discloses the use of carbonate materials such as coral which is converted into synthetic phosphate materials comprised predominantly of hydroxyapatite

Furthermore, White actually teaches away from forming products from coral as claimed by applicants. In the Background of the Invention, White states:

> The natural carbonate skeletal materials, however, such as calcite of Echinoid spine, or the aragonite skeletons are too brittle for many applications. This brittleness makes the natural carbonates particularly difficult to shape. They also lack the strength and durability required for some bone substitute applications.

Col. 1, ll. 29-35. According, White not only does not disclose a shaped product formed from a coral as claimed by applicant, White actually teaches against making such a shaped product.

The Examiner cites to AIMS only to show the ability of the *Acropora grandis* species to grow rapidly. It is the Examiner's contention that although White does not disclose using a coral of the species *Acropora grandis*, using this species of coral would have been obvious from the teaching of AIMS. However, as discussed above, White fails to disclose a shaped product formed from any coral species and actually teaches away from forming such a product. Accordingly, the combined teachings of White and AIMS do not disclose or make obvious the invention claimed in claim 4. Claims 5-7 and 11, which depend from claim 4, are patentable over White and AIMS for at least the same reasons.

Claims 8-10 stand rejected under 35 USC 103(a) as being unpatentable over White and AIMS, in view of Laurencin. This rejection is respectfully traversed.

Claims 8-10 depend from claim 4 and, accordingly, include all of the limitations of claim 4. As discussed above with respect to claim 4, White and AIMS fail to disclose a shaped product formed from coral as claimed by applicant. The Examiner cites Laurencin to show a hydroxyapatite bone composite having an antibiotic or growth factor incorporated into the hydroxyapatite. Laurencin, does not disclose or even mention a shaped product formed from coral. Accordingly, the combination of White and AIMS and Laurencin still does not disclose or suggest a shaped product formed from coral as claimed by applicants. Accordingly, the rejection of claims 8-10 should be withdrawn.

Finally, applicant notes that the U.S. patent to White *et al.* now cited by the Examiner as the primary reference appears to be directed to an improvement in the biomaterials disclosed in European Patent 0395187 also to White *et al.* The European patent was cited in the first Office Action, issued by the same Examiner as for the current

Office Action, back in June 2001. The newly cited U.S. patent discloses the inclusion of a polymer formed in situ in a porous ceramic based biomaterial such as a synthetic phosphate material. The synthetic phosphate material comprising hydroxyapatite, which can be made by converting calcium carbonate from coral, was discussed in European Patent 0395187. Accordingly, the recently cited U.S. patent to White is no more (and perhaps even less) applicable than the European patent to White previously cited. All of the rejections in view of the previously cited European patent were withdrawn by the Examiner following the response filed in August 2001.

For the foregoing reasons applicant requests that all outstanding rejections be withdrawn.

In the event that the transmittal letter is separated from this document and the Patent and Trademark Office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 229752001000.

Respectfully submitted,

Dated: April 29, 2004 By: _____

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